REMARKS

This application pertains to novel solid lipid particles of bioactive agents and methods for the manufacture and use thereof.

Claims 1-40, 42, 44 and 45 are pending; claims 41 and 43 being cancelled by this amendment.

Claims 1-15 and 37-39 have withdrawn from consideration by the Examiner as drawn to non-elected subject-matter. Applicants' election was made with traverse.

Reconsideration and withdrawal of the restriction requirement is respectfully requested for the reasons already stated in the response to the restriction requirement.

In case the Examiner still does not find it possible to withdraw the restriction requirement, it is respectfully requested that the non-elected subject matter be rejoined with the elected subject matter upon allowance of claims drawn to elected subject matter.

Claims 16-36 and 40-45 stand rejected under 35 U.S.C. 112, first paragraph because the Examiner reads said claims as reciting "at least one dispersant, coating material and optionally additives" and seems to believe that such terms are too broad. The language used in said claims is fully supported by the specification and although the scope of the claims may be broad, the language of the claims is fully supported by the specification. 35 U.S.C. 112 does not limit the breadth of a claim, and the present claims cannot be seen to violate 35 U.S.C. 112, first paragraph merely because the Examiner views the claims as having a broad scope.

All of the concerned "dispersants, coating materials and additives" are particularly disclosed in the description.

The Examiner's attention is respectfully drawn to MPEP 2163.04, which provides that the inquiry into whether the description requirement is met, must be determined on a case-by-case basis and is a question of fact (see In re Wertheim, 541 F.2d 257, 262, 191 USPQ 90, 96). A

description as filed is presumed to be adequate, unless or until sufficient evidence or reasoning to the contrary has been presented by the Examiner to rebut the presumption (see, e.g., In re Marzocchi, 439 F.2d 220, 224, 169 USPQ 367, 370), which in fact does not seem to be the present case, as outlined below.

The examiner has the initial burden of presenting by a preponderance of evidence why a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims (see Wertheim, 541 F.2d at 263, 191 USPQ at 97).

Looking at the cited section of MPEP 2163.04, and further taking into consideration MPEP 2163 3. (C) (1)-(2), which provides that, even if the Applicant did not describe an actual reduction to practice or reduction to drawings or structural chemical formula (which might be true for several dispersants, coating materials and additives), when the application as filed describes the complete structure of a species or embodiment of the claimed invention, the requirement under 35 USC § 112 that the description be set forth "in such full, clear, concise, and exact terms" to show possession of the claimed invention is fulfilled.

The description discloses complete structure of several species or embodiments of the claimed dispersants, coating materials and additives with reference to distinct functions and structures of these (See paras. [0049]-[0051] for the dispersants, [0052]-[056] for the coating materials and [0057], [0059]-[0098], [0099], [0100], [0101]-[0116], [0117], [0118], [0119], [0120] and [0121] for the additives). Accordingly there is no basis upon which the Examiner can rebut the presumption that the written description requirement has been fulfilled. The fact that a Claim seems to be broad can not be used to rebut the presumption.

Furthermore, Applicants respectfully point out, that the additives C) in independent Claims 16, 26 and 40 are consequently used optionally and that thus addition of the aforementioned limitations to Claims 16, 26 and 40 is not needed. The Claim prescribing use of these is Claim 42, which consequently has been amended as outlined before.

Nevertheless, amendments are made herein to obviate the concern raised by the Examiner that the Claims did not suffice to meet the written description requirement under 35 USC § 112 first paragraph (see below), which is hereby traversed by the Applicants.

More specifically, the limitations of dispersants [0049] and coating materials [0052] have been added to Claims 16, 26 and 40 to obviate the Examiners concerns.

Accordingly Claims 41 and 43 were deleted, as these already contained the more distinct limitations of dispersants and coating material.

Claim 42, has been amended to further comprise the limitations of [0058]-[0062] with regard to the penetrants, of [0099] with regard to the defoamers, of [0100] with regard to the low-temperature stabilizers, of [0101], [0109]-[0110], [0111]-[0112] with regard to the preservatives, of [0118] with regard to the redispersants, of [0119] with regard to the disintegrants, of [0120] with regard to the inert fillers and of [0121] with regard to the film formers.

Claims 16, 24, 26, 29, 34 and 40 have been amended in accordance with [0132] and [0133] of the disclosure, to correctly recite that an "emulsion" is formed in step c) of the inventive method, which subsequently is handled in steps d) and e).

No new matter is introduced.

It is believed that the rejection is obviated by the foregoing amendments, and the rejection of claims 16-36 and 40-45 under 35 U.S.C. 112, first paragraph should now be withdrawn.

Claims 16-36 and 40-45 stand rejected under 35 U.S.C. 103(a) as obvious over Westesen et al. (US 5,885,486) in view of Timothy et al. (Biotechnol. Prog. 2000, 16, 402-407).

Applicants again refer to the arguments made in response to the first office action wherein it was noted that the process according Westesen et al. does not only fail to disclose addition of compressible fluid in the supercritical state to the suspension, but additionally fails to

disclose the property of suspending at least one active substance A), which is solid at room temperature (...) in an aqueous phase.

The Examiner responds to this statement that Westesen et al. was not cited for addition of compressible fluid in supercritical state to the suspension, but Timothy et al. was cited for the addition of a compressible fluid.

However it is clear that Westesen et al. fails to disclose such addition of compressible fluid in supercritical state to the suspension. Furthermore the Examiner responds to the argument of the Applicants that the Westesen et al. reference does not disclose addition of active substance to an aqueous phase that, in contrast thereto, Westesen et al. discloses such addition to an aqueous phase.

The Examiner exemplifies "that a solid lipid or bioactive agent or a mixture of solid lipids is melted; stabilizers are added either to the lipid or bioactive agent or to the aqueous phase only depending on their physicochemical characteristics" (see. Col. 11, lines 6-30). Particularly from that quotation of the Examiner it becomes apparent that the bioactive agent is NOT added to the aqueous phase. It's the stabilizer that is added to the aqueous phase.

The active substance is always incorporated into the lipid melt, prior to contacting said mixture with the dispersion medium. Said contacting may be melting together with the lipid or dissolution, solution or dispersion in a lipid-melt (see col. 11, lines 16-20). From that it should be clear that nothing is "suspended" in an aqueous phase, as melts are liquids and thus cannot be suspended.

Considering, but for purely academic reasons, that such suspending would be feasible with a melt, by misinterpreting "suspending" as of meaning "dispersing" as to the Westesen et al. reference, the distinct sequence of Applicants Claims 16, 26 and 40 is not met by the Westesen et al. reference.

Accordingly, neither the limitation of Applicants Claims 16, 26 and 40, wherein "active

substance A) (...) is suspended in an aqueous phase" is met by the Westesen et al. reference, nor the subsequent steps a), b), c), d) and e).

Westesen et al. discloses an emulsification as to step c) of applicants inventive processes only with regard to a lipid melt, which becomes emulsified in a dispersion medium (see Col. 11, lines 25-30), which means that its never the active component being suspended and thereafter emulsified, but only the lipid melt.

The fact that the Applicants use an open ended comprising language of course does not preclude that other steps are admissible, but still the actual limitations in Applicants Claims need to be met by any reasonable combination of prior art references. Accordingly further steps might be added by the prior art before step a) and after step e), but the limitation of the sequence being fulfilled by a combination of prior art references needs to be met.

The Examiner does not explain how the Westesen et al. reference might meet either suspending or the sequence or how the Timothy et al. reference might help to overcome the discrepancies with regard to "suspending of the active substance in an aqueous phase" and with regard to the sequence of steps a) to e). The only argument presented by the Examiner is that the Claims of the Applicant are considered rather broad.

The only contribution of the Timothy et al. reference is found to be that the Timothy et al. reference discloses an addition of a gas in a supercritical state.

However the Timothy et al. reference only discloses addition of an active substance (Flurbiprofen) to supercritical CO_2 and expansion of the supercritical phase loaded with the active substance into an aqueous phase, comprising a surfactant (see p. 403, "Experimental Section; Phase behavior and rapid expansion from supercritical solution).

Hence the Timothy et al. reference fails to disclose suspending at least one active substance A), which is solid at room temperature (...) in an aqueous phase and further fails to disclose a sequence or part of a sequence, from which in combination with the Westesen et al.

reference Applicants sequence a) to e) according to Claims 16, 26 and 40 can be derived.

From the foregoing, it is clear that Applicants' claims are not unpatentable over Westesen et al. (US 5,885,486) in view of Timothy et al. (Biotechnol. Prog. 2000, 16, 402-407) and the rejection of claims 16-36 and 40-45 under 35 U.S.C. 103(a) as obvious over Westesen et al. (US 5,885,486) in view of Timothy et al. (Biotechnol. Prog. 2000, 16, 402-407) should now be withdrawn.

In view of the present amendments and remarks it is believed that claims 1-40, 42, 44 and 45 are now in condition for allowance. Reconsideration of said claims by the Examiner is respectfully requested and the allowance thereof is courteously solicited.

CONDITIONAL PETITION FOR EXTENSION OF TIME

If any extension of time for this response is required, Applicant requests that this be considered a petition therefor. Please charge the required petition fee to Deposit Account No. 14-1263.

ADDITIONAL FEE

Please charge any insufficiency of fee or credit any excess to Deposit Account No. 14-1263.

Respectfully submitted,
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Date: March 13, 2009

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